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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/834,307
Filing Date: April 12, 2001
Appellant(s): WHITBOURNE ET AL.

Ryan M. Flandro
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/4/09 appealing from the Office action mailed 5/28/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,589,120	KHAN et al	12-1996
5,980,550	EDER et al	11-1999
6,110,483	WHITBOURNE et al	08-2000
6,335,029	KAMATH et al	01-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 23-52,56-59,61-65,67,69-71,74,76-78 and 80-83 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Eder et al (USPN 5,980,550 hereafter '550) in view of Whitbourne et al (USPN 6,110,483 hereafter '483). The claims are drawn to a medicated device comprising a scaffold with defined edges along the surface that create openings, wherein a coating is applied that bridges said openings.

4. The '550 patent discloses a coated vascular implant comprising a water-soluble coating (abstract). The implant comprises a substrate and a coating wherein the coating comprises active agents that are delivered to the patient (col. 3, lin. 30-45). The implant has a coil shape where the edges of the coils form opening between them (Figures). The substrate may also be in the form of braided or woven wires (col. 5, lin. 43-55). These shapes would read on wire meshes.

The edges are bridges by the coating material (Figure 2 204). The coating connects the edges of the coils (Figures 2). The coating can comprise generally approved as safe polymers such as polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol and polyesters (col. 5, lin. 5-21). The implant comprises multiple layers (col. 5, lin. 60-68). The coatings can comprise both hydrophobic and hydrophilic polymers (col. 6, lin. 1-5). The stent comprise active agents such as aspirin and heparin (col. 6, lin. 10-15). The reference is however silent to the active agent loading of the implant. This loading is well known in the art and can be seen in the '483 patent.

5. The '483 patent discloses a medical device comprising a substrate with a coating (abstract, col. 5, lin. 58-65). The substrates include commonly difficult substrates to coat such as wires, needles, urethral inserts and other implantable objects (*Ibid.*). The coating material comprises both hydrophilic and hydrophobic polymers such as N-vinylpyrrolidone (col. 5, lin. 13-39) and acrylic polymers (col. 6, lin. 5-16) as well as vinyl acetate (*Ibid.*), as well as polyvinylpyrrolidone/vinyl acetate copolymers (col. 3, lin. 38-50). The coating comprises pharmaceutical agents including rifamycin, and heparin complexes with benzalkonium chloride (col. 8, lin. 59-col. 9, lin. 28). The coatings comprise from 0.01-20% of an active agent (col. 7, lin. 40-55). The coatings, as a result of the drying process, intermingle with the substrates (col. 10, lin. 36-40). The coating composition has a thickness of about less than 50 microns (col. 7, lin. 15-20). The thickness of this coating would possess a loading amount well within the limits of the claimed invention. The reference discloses various methods of making the medical device including dipping, spraying and other well-known coating methods (col. 2, lin. 60-68). Though silent to the specific design of the substrates regarding their edges and surfaces, the coating is a

continuous coating over each surface (col. 4, lin. 18-30). Applicant is invited to provide evidence that the continuous coating of the invention does not cover the edges and bridge surfaces.

6. The Specification indicates that multiple applications of the layer comprising 0.1% paclitaxel results in a loading of 50-60 micrograms/square cm of the medical coating layer when applied to a standard coil multiple times (Example 3). The Whitbourne patent exemplifies coating layer solution with 0.12% active agent (Example 18), that would result, through routine experimentation and application of multiple layers as suggested by Whitbourne (col. 9, lin. 50-60), in a loading within the limits of the claims. The prior art provides a similar coating layer comprising a similar concentration of active agent. Since a compound and it properties cannot be separated, the coating layers of the Whitbourne patent would inherently result in appropriate loading concentration since they have similar loading percentages to the coatings of the instant claims and comprise similar coating compounds.

7. Regarding claims 41 and 42, it is the position of the examiner that such limitations do not impart patentability to the claim. The reference discloses a polyvinylpyrrolidone/vinyl acetate copolymer as a possible coating material. It would be well within the limits of ordinary skill in the art to determine the optimal component ranges operation for the polymer coating giving the general conditions of the specification. The coating composition comprises the same hydrophilic polymers as the instant claims, and stabilizers that are hydrophobic and identical those of the instant claims, namely acrylates and cellulose nitrate (examples). The hydrophilic polymer is present in a concentration from 10-90% of the coating solution (col. 5, lin. 40-45), while the hydrophobic stabilizers are present in the in an amount from 0.01-20% (col. 7, lin. 55-58). The hydrophobic polymers are present in an amount at least as much as twice as much as the

hydrophilic polymers. It would have been obvious to optimize the concentrations and ratios of the coating polymer components in order to optimize the release of the active agents. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

8. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

9. With these things in mind it would have been obvious to a skilled artisan to follow the suggestions of the art to produce a medical article with a continuous coating over all surfaces with a high loading concentration. It would have been obvious to include the active agent loading of the '483 patent into the coated coil of the '550 patent in order to provide sufficient active agent able to provide sustained release and treatment. One of ordinary skill in the art would have been motivated to follow these suggestions in order to provide a coated medical device that is flexible, and resist wet abrasions. It would have been obvious to follow these suggestions with an expected result of a coated medical device.

10. Claims 50,53-55,60,61,66,72-75,77 and 79 rejected under 35 U.S.C. 103(a) as being patentable over the combined disclosures of Eder et al (USPN 5,980,550 hereafter '550) and

Whitbourne et al (USPN 6,110,483 hereafter '483) in view of Kamath et al (USPN 6,335,029 hereafter '029) and Khan et al (USPN 5,589,120 hereafter '120). The claims are drawn to a medical device comprising a substrate and a coating. The substrate is a coil, and the coating further comprises paclitaxel and other active agents.

11. As discussed above the '483 patent discloses a medical device comprising a substrate and a coating. The substrates include wires, stents, and other implants (col. 2, lin. 31-38). The reference is however silent to the inclusion of coils as possible substrates. The reference is also silence to the inclusion of paclitaxel. However the inclusion of this antibiotic is well within the level of skill in the art, since many antibiotic agents are mentioned and suggested by the '483 reference. Their inclusion in a medical device is well within the art as seen in the '029 reference.

12. The '029 reference discloses a coated medical device comprising a substrate and a coating with antibiotics agent incorporated therein (abstract). The substrates may include coils, (col. 2, lin. 45-50), biocompatible polymer coatings such as polyvinylpyrrolidone (col. 6, lin. 28-50), and antibiotics such as paclitaxel (col. 5, lin. 54-65). Following these teachings a skilled artisan would have been motivated to include paclitaxel in to the coating compositions of '483. A skilled artisan would have further been motivated to apply the coatings to a coiled substrate following the suggestions of '029.

13. Likewise as shown in the '120 reference, which teaches a coated implant comprising various antibiotics such as polyhexamethylene biguanide hydrochloride (col. 3, lin. 51-55). A skilled artisan would have been motivated to combine the agents of the '120 with the coatings in order to impart biocidal properties on the implant of '483.

14. With these things in mind a skilled artisan would have been motivated to apply coating compositions to coiled substrates as taught and suggested by '029, or '120. A skilled artisan would have been motivated to continuously coat the coil as taught by '483 in order to provide a medical device with a coating that is flexible, and resist wet abrasions. A skilled artisan would have been motivated to include paclitaxel into the coatings of '483 as shown in '029 and '120 in order to further treat more bacterial infections. It would have been obvious to a skilled artisan to combine these teachings and suggestions with an expected result of a medical device with a flexible and stable coating capable of treating various bacterial infections.

(10) Response to Argument

1). Applicant argues that the Eder reference does not disclose in any meaningful way the "bridging from one edge or surface of the substrate to another across the opening" as described in the instant claims. **2).** Applicant further argues that the Chamberlain Declaration dated 2/22/08 was not given proper weight and consideration. **3).** Applicant argues that in the Final Office Action, Applicant's arguments were not given their due weight regarding patentability. **4).** Lastly Applicant argues that Eder and Whitbourne have been misread and misapplied and do not obviate the instant claims.

1) and 3). Regarding theses arguments, it remains the position of the Examiner that first the combination of Eder and Whitbourne continue to obviate instant claims 23-52, 56-59, 61-65, 67, 69-71, 74, 76-78 and 80-83. The claims recite a medical device comprising a substrate comprising adjacent edges or surfaces in close proximity to each other defining openings, and a coating bridging or connecting the edges or surfaces to one another, along with a therapeutic agent being loaded at a concentration of 100 mg/square cm of coating. As seen in Figures 1 and

2, the Eder patent discloses a substrate comprising edges/surfaces that are in close proximity to one another that define openings. The windings of the coil define surfaces and edges in close proximity to one another. Also given the broadest reasonable interpretation, the end caps (104) also define surfaces in close proximity to each other. The continuous coatings on the surface of the coil connect both the end caps and the windings of the coil (Figure 2). Applicant asserts that the total disclosure of Eder (drawings and disclosure) would not teach bridging; however Applicant provides not support for this assertion. The disclosure indicates that the coatings are continuous. The device is a coil and comprises an inner and outer coating. The coatings, specifically the outer coatings exist on the surface of the substrate and connect one surface or rise of the coil to another (Figure 2). Applicant argues that this is a misreading of the disclosure and that the disclosure of the Eder does not support bridging as defined in the claims. However, "bridging" as defined by the claims, is a connection between two surfaces across an opening. The claims do not define the orientation of the "bridging" beyond connecting two surfaces. Thus any connection between two surfaces or edges defining an opening would qualify as bridging, meeting the limitations of the claims. The outer coating (part **206**) connects each rise of the coil implant. Further the end caps (parts **104**) are also surfaces that are in relative close proximity defining an opening where the outer coating connecting the parts across the opening defined by the space between the end caps. Given the broadest reason interpretation of the instant claim limitations, it remains the position of the Examiner that the continuous coating of the Eder coil would connect either the surfaces of the end caps (**104**) or the windings of the coil (**102**).

Regarding the interpretation of the Eder patent, Applicant asserts that Eder teaches away from the "bridging" of the instant claims by disclosing that the coating does not affect the shape

of the implant. Applicant argues that the bridging as alleged in the Office action would change the shape of the coil to that of a cylinder; however as can be seen from the Figures, the coil shape is retained in spite of the coatings. Applicant attempts to argue limitations that are not present in the claim. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., cylindrical shape of the coated coil) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case the claims do not specify that the medicated device once coated, is cylindrical in shape. The claims only require that the device comprise adjacent surfaces or edges, where the surfaces or edges are connected via a coating. It remains the position of the Examiner that any coating connecting two or more surfaces or edges, regardless of how that connection is made would constitute "bridging". The Specification provides no definition for the term bridging, nor is the shape definitively established. Regardless if whether the bridging between two surfaces follows the contours of those surfaces or edges or creates its own shape, as long as the surfaces or edges are connected by a coating layer, the claim limitations are met. It remains the position of the Examiner that the coatings of the Eder patent provide a continuous coating connecting the surfaces of the coil windings and connecting them. The coatings also connect the surfaces or edges of the end caps (104).

Regarding Whitbourne, the reference is applied to provide the specific polymers of the instant claims. Whitbourne discloses continuous coatings applied substrates similar to those of the Eder patent. It would have been obvious to apply the coatings of the Whitbourne patent to the

substrates of the Eder patent since the substrates are similar and the coatings applied in the Whitbourne are applied in a continuous fashion. The polymers of the Whitbourne patent would have provided an improved release for the active agents in the coating. The coatings would have been flexible and provide protection for the active agent. For these reasons the combination of the Eder and Whitbourne patent remains obvious.

2). Regarding the Chamberlain Declaration, as discussed in the Final Office Action the Declaration provides no objective evidence to support the opinion of Dr. Chamberlain. She is of the opinion that Figure 2 of the Eder patent is incorrect and does not in fact show the bridging of the instant claims. Dr. Chamberlain goes on to provide a "correct" schematic of the coil where the coating surrounds the individual windings and presents this a correct interpretation of the Figure in light of the disclosures. However this “correct” Figure is based on pure speculation, since no supporting disclosures are provided as evidence. Dr. Chamberlain provides no objective evidence to support this schematic, no disclosure from the Eder patent or statement from the inventor (Eder) to support the "correct" interpretation of the Figure. The fact that the Examiner disagrees with the Declaration and request further evidence does not mean the declaration was not considered. In fact the declaration was weighed, measured and found wanting. Dr. Chamberlain asserts that the Figure fails to account for the three dimensional nature of the coil, however as can be seen from the Figure the windings that rise from left to right are depicted as being in the foreground, and the windings falling left to right are depicted in the background. This would indicate that the rising windings are in front of the failing windings, and since the coil is continuous between the end caps the coil is in three dimensions. The declaration was not commensurate in scope with the instant claims since the declaration argues

limitations that are not present in the instant claims. ¶ 6 asserts that the Eder patent does not disclose bridging between the open areas between the coil windings, however the claims only require that coating "bridge" or connect across an opening defined by adjacent surfaces or edges, not an opening defined as the open space between the windings of a coil. As discussed above, the opening defined by adjacent edges or surfaces is met by the space between the end caps or the rises of the coil windings. Either way the coatings on the outer surface of the Eder coil provide a continuous path from one surface or edge to the other as seen Figure 2. Applicant was invited to provide evidence to support the "correct" Figure asserted by the Declaration. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Applicant has to date only provided a speculative drawing by an unrelated third party. The "correct" Figure is not supported by any disclosures in the Eder patent. Applicant has not established how a coating following the contours of the coil windings would change the shape of the coil or impeded its function. For these reasons the Declaration remains insufficient to overcome the instant rejection.

4) It remains the position of the Examiner that the combination of the Eder, Whitbourne and further supporting documents continue to obviate the instant claims. As discussed above the

Eder and Whitbourne patents disclose a coated medical device comprises adjacent surfaces or edges comprising a coating bridging the surfaces and edges. Regarding the drug loading, it remains the position of the Examiner that this limitation would have been an obvious to one of ordinary skill in the art and could have been arrived upon through routine experimentation. The active agents are loaded in an amount up to 20% of the coating composition. The coating composition is applied in a variable thickness from 2-100 microns. The coatings can be applied in multiple layers in order to achieve the desired drug release (col. 9, lin. 50-65). Through routine experimentation, the artisan of ordinary skill would have been able to arrive at the optimal loading concentration depending on the requirement of the stent. By applying multiple active agent layers loaded with up to 20% of an active agent, the loading concentration of at least 100-500 micrograms/square cm would be achievable through routine experimentation.

The Specification indicates that multiple applications of the layer comprising 0.1% paclitaxel results in a loading of 50-60 micrograms/square cm of the medical coating layer when applied to a standard coil multiple times (Example 3). The Whitbourne patent exemplifies coating layer solution with 0.12% active agent (Example 18) that would result, through routine experimentation and application of multiple layers as suggested by Whitbourne (col. 9, lin. 50-60), in a loading concentration within the limits of the claims. The prior art provides a similar coating layer comprising a similar concentration of active agent. Since a compound and its properties cannot be separated, the coating layers of the Whitbourne patent would inherently result in appropriate loading concentration since they have similar loading percentages to the coatings of the instant claims and comprise similar coating compounds. Since it would have been obvious to coat the coil of Eder with the coatings of Whitbourne, the combination would

have had coating layers with more than enough active agents present in the layers to result in loading concentration meeting the limits of the claims. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The knowledge to load coating layer with up to 20% active agents was established in the Whitbourne patent. The conversion of theses percent concentrations into loading concentrations of "microgram per square centimeter" is gleamed from the instant Specification, however the coating layers of the prior art and the instant claims are equally constructed and essentially comprise the same components. The reporting of different units of measure does not constitute a new feature of the same composition. For these reasons the claims remain obviated by the combination of the Eder and Whitbourne patents.

Regarding the remaining supporting references, the Kamath and Khan patents are not applied to address the coating bridging or drug concentration since as discussed above the Whitbourne and Eder patents meet these limitations. The Kamath and Kahn patents are applied to address the specific active agents recited in the claims, specifically antibiotics of claims 53 and 60. The Whitbourne patent discloses the use of gentamicin in the active coating layer and is suggestive of other antibiotics. It would have been obvious to include other antibiotics into the coating layer since the Whitbourne and Eder patents disclose the inclusion of similar active

agents into the coating layers. The Kamath and Khan patents establish the level of skill regarding the inclusion of these specific antibiotics into implant devices. As such it would have been within the level of skill in the art to combine these compounds into similar implant devices, in order to treat a variety of infection post implantation. For these reasons the claims remain obviated by the combination of the Eder, Whitbourne, Kamath and Kahn patents.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/MICAH-PAUL YOUNG/

Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/SREENI PADMANABHAN/

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